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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,860	01/28/2004	Kevin Stamp	7095MH-2	2988
22442	7590	03/14/2006	EXAMINER	
SHERIDAN ROSS PC 1560 BROADWAY SUITE 1200 DENVER, CO 80202			PRASAD, SONAL	
			ART UNIT	PAPER NUMBER
			3767	

DATE MAILED: 03/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

6

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/767,860	STAMP, KEVIN	
	<b>Examiner</b>	<b>Art Unit</b>	
	Sonal Prasad	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 January 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>7/6/04</u> .  | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-8, & 10-14, & 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Bloomberg (US 4,617,016). Bloomberg discloses an injection device comprising an outer housing (Fig. 1, #14) inside which is located a barrel (Fig.1, #6) for holding a dose of a medicament (claim 1, line1); a needle at one end the barrel (Fig.1, #7) and fixed with respect thereto, the needle and barrel being such that at least part of the needle is axially moveable in and out (Fig. 1, #7) of said outer housing but is biased to be normally wholly inside said housing; a plunger (Fig. 1, #10), axially moveable within the barrel (Fig. 1, #6); an inner housing intermediate the outer housing and the barrel and plunger, and an energy source (Fig. 1, #17) in communication with said inner housing, wherein the inner housing is moveable by the energy source between three positions, namely a first position in which the inner housing is in communication with both the plunger and the barrel such that, in use, the plunger and barrel are movable axially so as to move at least part of said needle out of the outer housing; a second position in which the inner housing is in communication with the plunger but not the barrel such that, in use, said plunger is movable axially into said barrel so as to expel medicament through the needle; and a third position in which the inner housing is in

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communication with neither the plunger nor the barrel such that, in use, the plunger and barrel are able to retract in order to retract the needle into the outer housing. (Figs. 1, 11, & 12)

Regarding claim 2, Bloomberg discloses an injection device wherein said inner housing includes one or more flexible tags, biased radially inwardly by communication with said outer housing. (Fig. 1, #8)

Regarding claim 3, Bloomberg discloses an injection device wherein one or more of said tags are situated at the rear end of the inner housing and are biased radially inwardly into communication with the plunger. (Fig. 1, #8 & #59)

Regarding claim 4, Bloomberg discloses an injection device wherein each rear tag is moveable out of communication with the plunger when aligned with a corresponding recess in the outer housing. (Fig 1, #30)

Regarding claim 5, Bloomberg discloses an injection device wherein each rear tag is substantially T-shaped. (Fig. 1, #8)

Regarding claim 6, Bloomberg discloses an injection device wherein one or more of said tags are situated at the forward end of the inner housing and are biased radially inwardly into communication with the barrel. (Fig. 1, #8, #59)

Regarding claim 7, Bloomberg discloses an injection device wherein each forward tag is moveable out of communication with the barrel when aligned with a corresponding recess in the outer housing. (Fig. 1, #8, #59, & #30)

Regarding claim 8, Bloomberg discloses an injection device wherein each rear tag is substantially L-shaped. (Fig. 1, #8)

Regarding claim **10**, Bloomberg discloses an injection device including means for allowing the inner housing to move axially only forward with respect to the outer housing. (detailed descrip 6)

Regarding claim **11**, Bloomberg discloses an injection device wherein said means is an arrangement of serrations intermediate the housings. (Fig. 1, #37)

Regarding claim **12**, Bloomberg discloses an injection device wherein said needle is biased to be normally wholly inside said housing by means of a spring intermediate the barrel and the outer housing. (Fig. 1, #32)

Regarding claim **13**, Bloomberg discloses an injection device wherein said needle, barrel and plunger are removable from said device.

Regarding claim **14**, Bloomberg discloses an injection device as claimed in any of the preceding claims further including a removable needle cover, which protects the needle during storage before use. (Fig. 1, #13)

Regarding claim **15**, Bloomberg discloses an injection device wherein said needle cover includes means for pulling a protective rubber sheath or the like from said needle when said needle cover is removed from the device. (Fig. 1, #13)

3. With regard to claim **17**, Bloomberg discloses the method of delivering an injection using an injection device. (Figs. 1, 11, &12)

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over

Bloomberg (US 4,617,016) in view of Anderson et al (US 2003/0000524.) The claim

differs from Bloomberg in disclosing the energy source. Anderson et al discloses the

energy source being a compressed gas. (Claim 42.) It would have been obvious at the

time of invention to one of ordinary skill in that art to make the energy source a

compressed gas as disclosed by Bloomberg and taught by Anderson to improve the

ease of use of the device.

#### ***Claim Rejections - 35 USC § 112***

1. Claims 16 & 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Both claims must be amended and must be more specific.

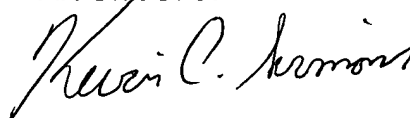
**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonal Prasad whose telephone number is 571-272-3383. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sonal Prasad  
Examiner  
Art Unit 3767



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